K061122

510(k) Summary

[As Required by 21 CFR 807.92(c)]

MAR 1 2 2007

1. Owner Information: [807.92(a)(1)]

Owner's Name:	Alpine Oral Care, LLC
Owner's Address:	4003 Leeland Ave Houston, TX 77003
Telephone:	(713) 223-8899
Fax:	(713) 223-0982
Contact Person:	Cathy Teng
Date Prepared:	02/15/07

2. Device Name: [807.92(a)(2)]

Trade Name:	NightGuard
Common Name:	mouth guard
Classification:	Mouth guards have yet to be classified.*

*Predicate products are classified under the following:
Device: Mouth guard
Product Code: MQC
Review Panel: Dental

3. Predicate Devices: [807.92(a)(3)]

Device	Applicant	510(k)	Decision Date
Doctor's Nightguard	Dental Concepts, LLC	K053580	03/03/06
Ez Splint & Ez Splin	Power Products, Inc.	K022809	10/17/2003
Dr. Hays Bite Guard	Inventive Resources, Inc.	K014079	02/22/2002

4. Device Description: [807.92(a)(4)]

NightGuard is a soft, comfortable, mouth guard intended to provide a barrier between the teeth for those patients who grind their teeth at night (bruxism). The product is shaped like a dental arch and is available in three sizes, but can be trimmed to fit more comfortably. **NightGuard is a full coverage device which covers the occlusal surfaces of all the upper teeth.**

5. Intended Use: [807.92(a)(5)]

The Night Guard is intended for protection against bruxism and nighttime teeth grinding. It is intended to reduce damage to teeth and to prevent the noise associated with bruxing and grinding

6. Comparison to Predicate Device: [807.92(a)(6)]

Narrative Comparison:

The NightGuard is composed of a soft thermoplastic resin. When the product is heated and cooled briefly the material can be molded to fit the upper teeth. The predicate devices, are the same or substantial equivalent in terms of design, material, chemical composition as outlined in the follow table.

Table: 3-1

Feature	**NightGuard**	**Doctor's Night Guard**	**Ez Splint PM**	**Dr Hays Bite Guard**
Indications for Use	The Night Guard is intended for protection against bruxism and nighttime teeth grinding. It is intended to reduce damage to teeth and to prevent the noise associated with bruxing and grinding	Same	Same	Same
Design	Adjustable Pre-formed oral device	Same	Same	Same
Materials	Thermoplastic Resin	Thermoplastic Resin	Elvax strap, polypropelene and kraton bite pads	Lexan & Evax
Method of Manufacture	Injection Molded	Same	Same	Dental Laboratory molded

				molded
Prescription Device	No	Same	Yes	Yes
Reusable	Yes, single patient	Same	Same	Same
Method of Desinfection	Warm water, soap and air dry	Same	Same	Same

7. **Non-Clinical Tests Performed [807.92(b)(1)]**

   No non-clinical tests were preformed for the determination of substantial equivalence.

8. **Clinical Tests Preformed [807.92(b)(2)]**

   No clinical tests were preformed for the determination of substantial equivalence.

9. **Conclusions Drawn From Non-Clinical and Clinical Tests [807.92(b)(3)]**

   No conclusions were drawn from Non-clinical and Clinical Test.

10. **Conclusion**

    NightGuard is as safe, as effective, and performs as well as or better than the predicated device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cathy Teng
Manager
Alpine Oral Care, LLC
4003 Leeland Avenue
Houston, Texas 77003

MAR 12 2007

Re: K061122
Trade/Device Name: Night Guard
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: MQC
Dated: February 23, 2007
Received: February 28, 2007

Dear Ms. Teng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

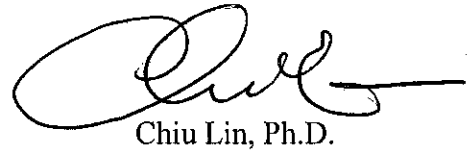
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061122

Indications for Use

510(k) Number : K061122

Device Name: Night Guard

Indications for Use:

The Night Guard is intended for protection against bruxism and nighttime teeth grinding. It is intended to reduce damage to teeth and to prevent the noise associated with bruxing and grinding.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use xx (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Susan Runner

K061122